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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte KARLHEINZ BORTLIK, FRANCOISE SAUCY, ELIANE DURUZ, MYRIAM RICHELLE, PIERRE LAMBELET, MARKUS BAUR, and ANDREA M.A. PFEIFER

Appeal 2008-6233[1]
Application 10/057,660
Technology Center 1600

Decided: February 2, 2009

Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 65-76, 78-82 and 86-93, all the claims remaining in the application. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] The real party in interest is Nestec S.A.

STATEMENT OF THE CASE

"The present invention relates to a primary composition comprising a lipophilic bioactive compound and a whey protein" (Spec. 3: 2-4).

The claims have not been argued separately, and therefore stand or fall together. We select claim 65 as representative of the claimed subject matter for the purpose of deciding all issues raised by this appeal. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 65 is as follows:

65. Primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound.

The Examiner relies on the following evidence:

Schmitz et al. ("Schmitz") US 5,643,623 Jul. 1, 1997

Appellants rely on the following evidence:

Affidavit of Karlheinz Bortlik, dated November 13, 2006, and originally submitted November 22, 2006, under the provisions of 37 C.F.R. § 1.132 ("Affidavit").

The Examiner rejected claims 65-76, 78-82 and 86-93 under 35 U.S.C. § 102(b) as anticipated by Schmitz.

We affirm.

ISSUE ON APPEAL

The Examiner found that Schmitz describes a "combination of whey and LBC [lipophilic bioactive compound] homogenized together in the amounts as claimed" (Ans. 6), that meets the structural limitations of the claims and inherently increases the bioavailability of the lipophilic bioactive compound (*id.* at 7).

Appellants contend that Schmitz "teaches including antioxidants in a lipid-based core . . . in an internalized and heterogeneous form, which is distinguishable from the homogeneous mixture of the LBC and whey protein in accordance with the present claims" (App. Br.[2] 11), and which "does not inherently posses[s] the advantages of the present claims" (*id.* at 14).

The threshold issue raised by this appeal is as follows: Has the Examiner established a reasonable factual basis for finding that Schmitz's homogenized combination of whey and antioxidants meets the structural and functional requirements of the claimed mixture of whey and lipophilic bioactive compounds, thereby shifting the burden to Appellants to establish it does not? If so, the residual issue is: Have Appellants carried their burden?

FINDINGS OF FACT

FF1 Appellants invented an oral composition comprising a "mixture" of at least one lipophilic bioactive compound (LBC) and a whey protein, where the whey protein is present in an amount sufficient to increase the bioavailability of the LBC (Claim 65).

FF2 The claims use the open transitional term "comprising" and do not preclude the presence of additional components in the mixture.

FF3 The Specification teaches that LBCs include carotenoids (particularly lycopenes), lipophilic vitamins, curcuminoids, and retinoids (Spec. 4: 3-14).

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[2] All references to the Appeal Brief are to the corrected Appeal Brief filed May 16, 2007.

FF4 The Specification teaches that "the present invention provides a composition comprising a lipophilic bioactive compound which has a better bioavailability than the compound alone" (Spec. 5: 11-14). According to the Specification, whey protein in the composition "protect[s] and preserve[s] the activity of the lipophilic bioactive compound" (*id.* at 19-20).

FF5 The Specification teaches that "the lipophilic bioactive compound is preferably present in an amount of about 0.05 to 50% by weight of the [primary] composition and the whey protein is present in an amount of about 5 to 90% of the composition. Also, the whey protein and lipophilic bioactive compound may be present in a weight ratio of at least about 1:1 to 500:1, preferably from about 1.5:1 to 250:1 and more preferably about 2:1 to 20:1" (Spec. 6: 10-18).

FF6 The Specification teaches that "[t]he composition additionally comprises one or more of emulsifiers, stabilizers and other additives . . . such as phospholipids" (Spec. 5: 32-35).

FF7 The Specification does not explicitly define the term "mixture," but teaches that "[t]he process for the preparation of a primary composition comprises associating the whey protein with the lipophilic bioactive compound under conditions sufficient to form . . . a mixture" (Spec. 2: 20-23). For example, "[t]he composition may be formed by dissolving the whey protein in water to form a first solution, dissolving the lipophilic bioactive compound in a solvent to form a second solution, combining the two solutions, and evaporating the solvent" (*id.* at 2: 23-28). Alternatively, "the lipophilic bioactive compound, either in the oleoresin form or in the powder form or in any other dry form . . . is mixed directly with the whey

powder . . . to produce the primary composition according to the invention" (*id* at 10: 5-11).

FF8 The Examiner rejected claims 65-76, 78-82 and 86-93 under 35 U.S.C. § 102(b) as anticipated by Schmitz.

FF9 Schmitz describes "a food product which comprises a first component and a second component, wherein the first component is in the form of a discrete portion from the second component" (Schmitz, col. 2, ll. 60-63).

FF10 Schmitz's "first component comprises an antioxidant . . . in addition to a carbohydrate and/or fat and/or protein" (Schmitz, col. 2, ll. 63-65), and "[p]referably . . . a lipid-based carrier to promote absorption of the lipid-soluble antioxidants in the gastrointestinal tract" (Schmitz, col. 5, ll. 25-27).

FF11 Schmitz teaches that the antioxidant blend can include various lipid-soluble compounds, for example: carotenoids (including lycopenes), curcumin, and vitamin E (Schmitz, col. 2, ll. 55-56 and col. 3, ll. 6-14). These are the same as the "lipophilic bioactive compounds" required by the present claims.

FF12 Schmitz's second component comprises carbohydrate, fat, and/or protein, as well as other nutritive and non-nutritive components (Schmitz, col. 5, ll. 40-43).

FF13 Schmitz describes a food product with a "first component" comprising 10-20% whey protein, 0.1-1.0% carotenoid blend, 0.1% turmeric extract, and 1-5% vegetable oil, etc., and a discrete "second component," also comprising whey protein (Schmitz, col. 8, ll. 10-30; Example 6).

FF14 Schmitz teaches that the "[i]ngredients for the first component are blended in such a way that the antioxidant compounds are dispersed in the lipid-based carrier and then mixed with the remaining ingredients . . . the resultant mixture advantageously contains a homogeneous mixture of antioxidant compounds" (Schmitz, col. 6, ll. 17-25). Similarly, the "[i]ngredients for the second component . . . are blended in such a way that the resultant mixture is well mixed" (Schmitz, col. 6, ll. 25-28). "The first and second components are metered through a co-extruder in such a way that the first component is delivered as an internalized core within the second component" (Schmitz, col. 6, ll. 29-32).

FF15 Schmitz describes a food product in which the first component comprises a homogeneous mixture of whey protein and antioxidants. The antioxidants are the same as the LBCs required by the claimed invention, and the whey protein and the antioxidants/LBCs are combined in proportions asserted in the present Specification to be sufficient to increase the bioavailability of the antioxidants/LBCs (FF5, 11, 13, 14).

FF16 The Examiner found that Examples 5 and 6 of Schmitz "clearly teach a homogeneous blend of whey and LBC . . . [in] the first component" (Ans. 6), in the claimed amounts, which "necessarily perform[s] the functions" required by the claims (*id.* at 7).

PRINCIPLES OF LAW

"[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000).

> [T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary

> usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997). However, the claims are not to be confined to the embodiments found in the Specification, and it is improper to import limitations from the Specification into the claims. *In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007).

"[T]he Patent Office has the initial burden of coming forward with some sort of evidence tending to disprove novelty." *In re Wilder*, 429 F.2d 447, 450 (CCPA 1970). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or *inherently* described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) (emphasis added). "[I]t is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." *In re Best*, 562 F.2d 1252, 1254 (CCPA 1977) (quoting *In re Swinehart*, 439 F.2d 210, 212-13 (CCPA 1971)).

"[W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on." *Id.* at 1254-55. That is, "when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the

applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).

ANALYSIS

The Examiner rejected claims 65-76, 78-82, and 86-93 under 35 U.S.C. § 102(b) as anticipated by Schmitz.

The Examiner has provided ample evidence to support her conclusion that the first component of Schmitz's food product contains a mixture of whey protein and LBCs, in proportions sufficient to increase the bioavailability of the LBCs, properly shifting the burden to Appellants to establish otherwise.

Appellants note that "several examples [in the Specification] illustrate that the whey protein may be dissolved in a solvent. Similarly, the LBC may also be dissolved in another solvent . . . the solutions are then mixed before the solvents are evaporated" (App. Br. 11). Thus, Appellants contend, "one having ordinary skill in the art would understand that the LBC of the present claims is mixed into and throughout the whey protein matrix in a homogeneous manner (i.e., there is no discrete separation of the LBC and the whey protein)" (*id.* at 12). Appellants contend that Schmitz, in contrast

> discloses a health food product containing a first component in the form of a discrete portion (i.e. core) from a second component. . . . [and] one having ordinary skill in the art would not use the term "mixture" when describing the relationship of a first . . . inner core and a second outer component of a product. Instead, they would be considered adjacent or discrete. A "mixture," on the other hand, refers to a greater level of integration of the two components rather than placing them next to each other.

(*Id.*) Appellants further contend that Schmitz "entirely urges use of a lipid-containing core and does not teach that the lipid core may be replaced by a whey protein matrix" (Reply Br. 5).

Appellants' arguments are not persuasive. First, we note that the present Specification teaches that simply mixing the LBC "either in the oleoresin form or in the powder form or in any other dry form . . . directly with the whey powder" is sufficient "to produce the primary composition according to the invention" (Spec. 10: 5-11; FF7). Second, it is true that Schmitz describes a food product with a first component in the form of an inner core comprising antioxidants in a lipid based carrier, and a discrete second component comprising whey protein "adjacent" or "next to" the internal core (FF9, 10, 13, 14). However, the *first* component of Schmitz's food product also contains whey protein (FF13), and Schmitz explicitly states that the ingredients for the first component are homogeneously mixed. Specifically, Schmitz teaches that the antioxidants (i.e., the lipophilic bioactive compounds) and the lipid-based carrier of the first component are pre-blended so that the antioxidant compounds are dispersed in the lipid-based carrier, and the dispersion is combined with the remaining ingredients of the first component, including whey, to produce a "resultant mixture [which] advantageously contains a homogeneous mixture of antioxidant compounds" (FF14). Thus, all of the ingredients in the completed first component, including the antioxidants and the whey protein, are homogeneously mixed, i.e., integrated. Moreover, there is nothing in the present claims that precludes combining the lipophilic bioactive compounds with whey *and* a lipid-based carrier (FF2, 6).

Finally, we have considered the Affidavit of inventor Karlheinz Bortlik, but are not persuaded that it demonstrates that "*Schmitz* does not inherently posses[s] the advantages of the present claims" (App. Br. 14).

In the Affidavit, Dr. Bortlik states that he "believe[s] that *Schmitz's* product does not achieve enhancing bioavailability of the LBC with whey protein" (Affidavit ¶ 7) because "the antioxidants in *Schmitz's* composition are in an internaliz[ed] and heterogeneous form" (*id.* at ¶ 6) "in a lipid-based carrier" (*id.* at ¶ 7), while "the LBC is distributed uniformly throughout the whey protein in the present invention" (*id.*).

Again, this assertion is not persuasive. Schmitz describes a homogeneous mixture of whey protein and antioxidants (FF14). The antioxidants are the same as the LBCs required by the claimed invention, and the whey protein and the antioxidants/LBCs are combined in proportions asserted in the present Specification to be sufficient to increase the bioavailability of the antioxidants/LBCs (FF5, 11, 13). The Examiner has properly shifted the burden to Appellants to establish that Schmitz's first component mixture does not inherently increase the bioavailability of the LBCs. Appellants have not carried that burden.

CONCLUSION OF LAW

The Examiner has established a reasonable factual basis for concluding that Schmitz's homogenized combination of whey and antioxidants meets the structural and functional requirements of the claimed mixture of whey and lipophilic bioactive compounds, and Appellants have not carried their burden of proving otherwise by argument or evidence.

SUMMARY

We affirm the Examiner's rejection of claims 65-76, 78-82, and 86-93 under 35 U.S.C. § 102(b) as anticipated by Schmitz.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

Ssc:

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